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No. 98-1768

IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONER THE BUCKMAN COMPANY

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.[2] These companies produce the majority of new medicines that are developed and marketed throughout the world. A number of PhRMA's members also are engaged in the development and sale of medical devices.

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1. This brief was authored by the *amicus* and counsel listed on its cover, and was not authored in whole or in part by counsel for a party. No one other than the *amicus* or its counsel made any monetary contributions to the preparation or submission of this brief. This brief is being filed in accordance with a consent agreement entered into by both parties, which has been filed with the Clerk.

2. PhRMA's brief is submitted on behalf of PhRMA members Abbott Laboratories, Allergan, Inc., ALZA Corporation, American Home Products Corporation (and subsidiaries), Amgen, Ares-Serono International, AstraZeneca LP, Aventis Pharma AG, Bayer Corporation Pharmaceutical Division, Biogen, Inc., Bio-Technology General Corp., Boehringer Ingelheim Corporation (and subsidiaries), Bristol-Myers Squibb Company (and subsidiaries), E.I. duPont de Nemours and Company, Elan Pharmaceuticals (and subsidiaries), Fujisawa Healthcare, Inc., Genentech, Inc., Genzyme Corporation, Gilead Sciences, Inc., Glaxo Wellcome Inc., Hoffman-La Roche Inc., Immunex Corporation, Johnson & Johnson (and subsidiaries), Knoll Pharmaceutical Company, Eli Lilly and Company, Merck & Co., Inc. (and subsidiaries), Novartis Pharmaceuticals Corporation, Nycomed Amersham Imaging, Organon Inc., Otsuka America Pharmaceutical, Inc., Pfizer Inc., Pharmacia Corporation, The Procter & Gamble Company, Purdue Pharma L.P., Sanofi-Synthelabo Inc., Schering-Plough Corporation, SCHWARZ PHARMA, Inc., SmithKline Beecham (and subsidiaries), Solvay Pharmaceuticals, Inc. and 3M Pharmaceuticals.

PhRMA's member companies will invest almost $26 billion this year in discovering and developing new medicines, leading the way in the search for cures. PhRMA estimates that the current average cost of developing a single new drug is approximately $500 million, and that the development process requires about fifteen years.[3] This lengthy development period already cuts significantly into the patent protection period that affords manufacturers their best opportunity to recover these enormous development costs. Opening the door to additional pre-approval burdens arising under state law, and casting doubt on the finality of federal device and drug approvals, would diminish the economic incentive for new device and drug development.

PhRMA's members are concerned that the lower court's decision, unless reversed, would improperly permit the states, through common-law fraud actions, to add a second, state-administered Food and Drug Administration (FDA) approval process. Allowing state courts and juries to second-guess FDA approval decisions would undermine the certainty and uniformity of the federal approval scheme, upon which manufacturers rely in developing and marketing their products. Moreover, the specific distortion of the federal regulatory regime upon which respondents' claims are based would, in practice, delay, or even eliminate, the availability of many new and competitive devices and drugs, to the detriment of PhRMA's members and the public health.

For these reasons, PhRMA joins petitioner The Buckman Company in urging this Court to reverse the lower court's holding on the question presented for review.

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3. This total includes time spent on (1) "pre-clinical" testing; (2) clinical testing of the drug on human populations; and (3) applying for and awaiting final FDA approval.

STATEMENT OF THE CASE

In the interest of judicial economy, PhRMA adopts the statement of the case as set forth in petitioner's brief.

SUMMARY OF ARGUMENT

The Medical Device Amendments of 1976, 21 U.S.C. § 360k(a) (MDA), to the Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §§ 301-397 (FFDCA), expressly and impliedly preempt respondents' claims. The lower court's holding to the contrary should be reversed.

The lower court erred in holding that the present case is controlled by *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). In so doing, the lower court wrongly opened the door to disruptive second-guessing of FDA approval determinations by state courts, juries, and administrative agencies. At most, *Medtronic* holds that, where the federal regulatory regime governing medical devices has accorded broad discretion to manufacturers (such as in the design and manufacture of products), the MDA does not preempt the states from "filling in the gaps" in federal regulation by enforcing traditional common-law standards of behavior.

Here, however, respondents' state-law claims do not arise from traditional areas of state authority. Rather, they are premised on the peculiar theory that liability under state law arises from fraud on a *federal* agency. Nor do the state-law claims concern matters on which the federal regime has failed to speak or has given discretion to manufacturers. To the contrary, respondents' claims rest on a challenge to the validity of an *FDA approval determination* — a specific, adjudicative ruling by the FDA with respect to the device at issue. Thus, *Medtronic* does not control in this case.

Respondents' claims must be preempted. These claims challenge the legality of marketing an FDA-approved product. If state law could support such claims, plaintiffs

who believe that their injuries are associated with the use of any FDA-approved product could assert that the product was approved only because of "fraud," other alleged manufacturer misconduct, or because the FDA "got it wrong." Although federal law gives finality to FDA premarketing approvals, claims such as respondents' effectively add state approval requirements to this federal review. By imposing a state-law requirement different from, and in addition to, the federal requirement, recognition of respondents' claims would directly contravene § 360k(a).

State-based collateral review of FDA approval decisions also interferes with the legislative purposes of the FFDCA and MDA. The federal regulatory regime governing approval of devices and drugs accords uniformity and finality to the FDA approval process. In the premarket approval context, the FDA grants market access to a device or drug only after careful consideration of the product's possible benefits versus its potential risks for the labeled uses. Once the approval determination has been made, the product's manufacturer[4] enjoys the certainty that it may lawfully market its product in interstate commerce, so long as it does so in accordance with the approved labeling. This certainty is essential to facilitating the research, development, and marketing of new, innovative medical products, all of which carry possible risks, and none of which can be proven safe and effective in all circumstances.

Permitting state review of the FDA approval process would turn this system on its head. Even where, as here, the states purport to follow federal approval standards in assessing the validity of an FDA approval decision, the states may interpret those approval criteria inconsistently with

4. In this brief, "manufacturer" is intended to encompass manufacturers of medical devices and pharmaceuticals, as well as the regulatory agents of those manufacturers (such as petitioner).

Congressional intent or FDA practice. Manufacturers then would be faced with enormous and unfair potential liability for failing to comply with the *ex post facto* interpretation of the approval standards adopted by each state (or each state court or jury). As a result, a dual regime could radically delay, or even preclude, the introduction of beneficial new products.

This case aptly illustrates the adverse consequences of permitting state review of FDA approval decisions. Respondents' state-law claims are premised on the theory that the availability of petitioner's bone screws *itself* caused them harm, and that the FDA "got it wrong" in approving the screws as labeled due to petitioner's alleged fraud. If allowed to proceed, these claims would require state courts and juries to inquire into whether, in fact, the FDA "erred" in allowing the screws to be marketed.

In order for respondents to prevail, moreover, the reviewing state courts and juries would necessarily have to adopt an interpretation of federal standards *different* from that which has been adopted by Congress. Specifically, respondents assert that federal law requires an applicant for FDA approval to "truthfully" disclose to the FDA its subjective intent or expectation regarding the product's use. Since the early federal food and drug laws, however, Congress has made clear that the "intended use" statement in a premarket notification application is an objective description of the claims made in the labeling. Congress's objective construction of "intended use" reflects its long-standing effort to regulate the promotional claims made by manufacturers, rather than to interfere with the freedom of physicians to practice medicine in accordance with their professional judgment.

By necessitating, under state law, a broader construction of "intended use" than that intended by Congress, respondents' claims would inevitably expand the scope of

testing and review required for the approval of new drugs and devices. In addition, where off-label uses develop for such drugs and devices, as is commonly the case, respondents' broader construction of "intended use" would foreclose use of the "§ 510(k)" and Abbreviated New Drug Application processes established by Congress to accelerate new entry. Respondents' construction also would interfere with the delicate federal regulatory balance governing the dissemination of information regarding off-label uses.

The Supremacy Clause, U.S. Const., art. VI, cl. 2, and the Medical Device Amendments require preemption of state-law standards that permit the states to scrutinize the FDA approval process and second-guess the validity of FDA approval determinations. These standards, whether imposed through common-law causes of action or statutory schemes, would impermissibly disrupt the intended uniformity and certainty of the federal approval regime, and could lead to reduced availability of important medical products.

ARGUMENT

I. THE LOWER COURT WRONGLY OPENED THE DOOR TO SECOND-GUESSING OF FDA APPROVAL DETERMINATIONS BY STATE COURTS, JURIES, AND AGENCIES.

Respondents' state-law claims against petitioner are premised on the *very availability* of petitioner's bone screws. Without such availability, respondents claim, the surgical procedures that allegedly caused their injuries would never have been performed. Put another way, respondents assert that the FDA "got it wrong" in approving petitioner's bone screws, because the screws never would have been approved absent petitioner's alleged "fraud" during the approval process. Respondents thus seek to use their "fraud on the FDA" claims to set aside the FDA's determination that the screws at issue were entitled to a § 510(k) approval, *see* 21 U.S.C. § 360e(b)(1)(B), and could lawfully be marketed.

The court below, reversing its earlier position in *Michael v. Shiley*, 46 F.3d 1316 (3d Cir. 1995), permitted respondents' claims to go forward over preemption challenges. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 819, 823 (3d Cir. 1998). The majority believed that this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), required this result because (a) respondents were not challenging a specific federal requirement with respect to a device; and (b) respondents' challenge was premised on a federal standard of candor and thus supported, rather than contradicted, federal goals. 159 F.3d at 823. The lower court was wrong in both respects.

A. *Medtronic* Does Not Control This Case.

Medtronic is inapplicable in this case. At most, *Medtronic* stands for the proposition that, where the federal regulatory regime governing medical devices provides manufacturers with broad discretion in designing and manufacturing their products, the states are not precluded from "filling in the regulatory gaps" by imposing traditional common-law duties and statutory standards. 518 U.S. at 500-01 (plurality opinion); *id.* at 508 (Breyer, J., concurring in part and concurring in the judgment).[5] A majority of this Court in *Medtronic* concluded that the plaintiff's state-law negligence and product liability claims were not preempted by the MDA, 21 U.S.C. § 360k(a), because there were no specific federal regulations governing the manufacture or design of the device in question. 518 U.S. at 501 (plurality opinion); *id.* at 508 (opinion of Breyer, J.). The plurality opinion noted that the case at bar was

> quite unlike a case in which the Federal Government has weighed the competing interests

5. PhRMA recognizes that petitioner's brief asks this Court to reconsider its holding in *Medtronic*. Such reconsideration may in fact be appropriate in this case.

> relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.

Id. at 501.

In this case, the federal government (*i.e.*, the FDA) has made a *specific* determination that petitioner's device is entitled to be sold as labeled. Thus, the FDA has "reached an unambiguous conclusion" in a "particular case," and "implemented that conclusion via a specific mandate on [petitioner]" — by granting § 510(k) approval. *See id.*

Indeed, FDA device approval determinations necessarily involve federal actions specific to a device, as they are decided on a case-by-case basis on the strength of a manufacturer's § 510(k) application or premarket test data. Further, the federal regulatory regime governing device approvals does not confer discretion on manufacturers with respect to initiating marketing, or leave "gaps" for states to fill with common-law causes of action: an FDA approval determination is the final word regarding whether a product may or may not be marketed in interstate commerce as labeled.

Moreover, respondents' claims are of a different character from those in *Medtronic*. *Medtronic* involved state-law claims in areas of traditional state concern; *i.e.*, product liability and negligence. 518 U.S. at 481. Here, by contrast, respondents' claims are based on the odd premise that liability under *state* law may arise when an actor commits "fraud" on a *federal* agency. Certainly, the relationship between federal agencies and those they regulate is not a field of historic state concern or legislation. *See* Brief of United States, at 15. Thus, the "assumption that the historic

police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress" does not apply here. *Medtronic*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

Because this case involves an attempt to overturn a specific federal approval determination, using a non-traditional theory of state-law liability based solely on alleged violations of federal duties, *Medtronic* cannot control its outcome.

B. State-Law Causes Of Action Or Standards Permitting Collateral Review Of FDA Approval Decisions Must Be Preempted.

In sustaining respondents' claims, the court below wrongly opened the door to second-guessing of federal approval determinations by state courts, juries, and administrative agencies.

These claims, resting on the alleged invalidity of FDA approval decisions, add a layer of state-based review to the FDA approval process. They permit the states to examine and determine whether the FDA was caused to err in granting market access. This would, in turn, allow states, through the imposition of massive civil liability, to effectively override the FDA's approval decision.

This type of claim inherently runs afoul of the Constitution's Supremacy Clause. U.S. Const., art. VI, cl. 2; *see also Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (the Supremacy Clause requires preemption where state law conflicts with federal law or "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"). The federal regime confers primary enforcement jurisdiction on the FDA, the purpose of which is to accord finality to the agency's approval determinations. *See* 21 U.S.C. §§ 371(a), (h), 393 (charging the FDA with

enforcement jurisdiction over the FFDCA and MDA, and particularly with ensuring that drugs and medical devices are safe and effective). This finality provides manufacturers with certainty that they may lawfully place their products in interstate commerce. Finality is critical to the approval process, which, as it stands, involves tremendous cost and risk to applicants.

Applicants for FDA approval frequently spend many years and millions of dollars researching, developing, and testing new products before the FDA approval process even begins. Obtaining approval often means spending millions more in testing or running clinical trials. *See* Robert Samuelson, *Beware of a Regulatory Overdose*, Wash. Post, Sept. 5, 2000, at A25 (citing studies reporting that, on average, developing a new drug costs from $200 to $500 million and takes about 15 years). Further, the time spent in seeking FDA approval cuts into the statutory patent protection period afforded to new, innovative products. *See* 35 U.S.C. § 154; *see also* Deirdre Davidson, *Reform Eyed For Landmark Drug Law*, Legal Times, Sept. 11, 2000, at 1 (citing study reporting that pharmaceuticals enjoy an average of 11.5 years of patent protection, while other types of products are protected for an average of 18 years). The longer the process takes, the less time a manufacturer has to market its product on an exclusive basis and recoup its development costs.

In reviewing a premarket approval application for a medical device or drug, the FDA carefully balances the potential benefits and possible risks of the product in question for its labeled uses. *See* 21 U.S.C. §§ 355(d), 360e(d); *see also* Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049, 2075 (2000). Both the FDA and the applicant know that no product for which approval is sought can be proven entirely safe or effective; the FDA's role is to decide whether the product's potential health

benefits for the proposed uses outweigh its possible dangers. If the FDA so determines, it will approve the product to be marketed for the uses specified in proposed labeling. 21 U.S.C. §§ 355(d); 360e(d).

Allowing state courts and juries to "look behind the labeling" and second-guess FDA approval determinations would turn this system on its head. The *very existence* of state-based re-evaluations of the FDA approval process subverts the finality of the FDA's decisions. Any time the use of an FDA-approved product allegedly causes harm, plaintiffs could assert, as here, that the federal approval decision was erroneous, whether due to "fraud," FDA mistake, or for other reasons. The FDA approval determination would then be subject to intrusive scrutiny by state courts and juries. Even assuming that the states purported to follow *federal* standards in examining the approval process, the states might interpret such standards differently from Congress and the FDA. Permitting such an inquiry would raise the significant possibility that FDA approval determinations would be judged "invalid" by state decision-makers. The question of whether any given federal approval decision was valid also could be answered differently from court to court and from jury to jury, leaving the approval status of a medical device or drug entirely up in the air.

Additionally, allowing common-law challenges to FDA approvals could open the door to state administrative schemes designed to provide collateral review of FDA approvals. If common-law, *de facto* challenges to FDA approval decisions are permissible, it might be difficult to prevent a state from establishing an administrative scheme to review FDA approvals before permitting in-state marketing. As a result, manufacturers could find themselves forced to apply for approval in *each state* before being able to market a product in interstate commerce.

Permitting state collateral review of federal approval decisions would impermissibly disrupt the federal approval system. Manufacturers could no longer rely on FDA approval determinations in marketing their products. Rather, because they could face *ex post facto* state-based challenges to FDA approval decisions (leading to potentially enormous liability under state law), manufacturers would be left with massive uncertainty regarding the legality of marketing any given product. This uncertainty could have severe and adverse effects on the research and development of medical devices and drugs: because the risks associated with new products would be exponentially higher, many potentially beneficial devices and drugs might never be developed.

The Supremacy Clause, U.S. Const., art. VI, cl. 2, does not permit state law to undermine the finality of FDA approval determinations in this manner. The Supremacy Clause mandates preemption of state common-law or legislative standards that permit scrutiny of the federal regulatory process and challenges to the approval determinations that result therefrom. *See Leslie Miller, Inc. v. Arkansas*, 352 U.S. 187, 190 (1956) (per curiam) (invalidating the application of a state licensing requirement to federal contractors whose bids had been approved under federal criteria; such a requirement gives the state "a virtual power of review over the federal determination," and "does not merely touch the Government servants remotely by a general rule of conduct; it lays hold of them in their specific attempt to obey orders and requires qualifications in addition to those that the Government has pronounced sufficient") (quoting *Johnson v. Maryland*, 254 U.S. 51, 57 (1920)).[6]

6. Several lower courts have recognized this principle. *See, e.g., Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1505 (11th Cir. 1997), *cert. dismissed*, 523 U.S. 1113 (1998); *Mitchell v. Collagen Corp.*, 67 F.3d 1268, 1283 (7th Cir. 1995) (the MDA preempted plaintiffs' "fraud on the FDA" claims because such claims "require[] (Cont'd)

In addition, the express preemption provision of the MDA, 21 U.S.C. § 360k(a), requires preemption of this category of claims in the context of medical devices. A state-law claim that requires the collateral review of the FDA's approval decision with respect to a device necessarily imposes a requirement (*i.e.*, another stage of review) that is "different from, or in addition to," the requirements for federal approval. In other words, once a device has, in the FDA's view, met the federal criteria for approval, section 360k(a) precludes a state from adding the effective requirement that the device satisfy *state*-administered premarket criteria.

Preempting state actions that permit re-evaluation of FDA approval decisions would not mean that "fraud on the FDA" or other unlawful conduct occurring during the approval process would go uncorrected or unpunished.

(Cont'd)
a court, applying state law, to perform the same functions initially entrusted to the FDA") (quoting *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir. 1995)), *judgment vacated*, 518 U.S. 1030 (1996), *on remand*, 126 F.3d 902 (7th Cir. 1997); *Talbott v. Bard, Inc.*, 63 F.3d 25, 29 (1st Cir. 1995) (noting the disruptive effect that state "fraud on the FDA" claims would have on the uniformity of FDA decisions, and observing that the FDA has "broad" authority to withdraw approval decisions and initiate criminal prosecutions against manufacturers who commit fraud); *Reeves v. Acromed*, 44 F.3d 300, 307 (5th Cir. 1995) ("Allowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent in § 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers"); *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 666 (7th Cir. 1997) (finding state "misbranding" claims against herbicide manufacturer preempted where manufacturer's label conformed with EPA-approved label; "FIFRA does not allow states to second-guess EPA's labeling decisions under the guise of enforcing the requirements of FIFRA itself"), *cert. denied*, 523 U.S. 1137 (1998).

The FDA has primary responsibility for policing violations of its regulations. It also has ample authority to withdraw approval and/or seek criminal penalties where it finds that violations have been committed. *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985).[7] Given its central role in reviewing and approving devices and drugs, the FDA is in the best position to decide whether a "fraud" or other wrong has occurred, and, if so, how the culpable party should be penalized.[8]

The integrity of the FDA approval regime requires preemption of state-law standards — including respondents' "fraud on the FDA" claims — that permit *ad hoc* (or systematic) challenges to the validity of FDA approval decisions. Allowing such standards to exist would undermine the finality and uniformity of federal approval decisions, and, as a result, distort manufacturer behavior in a manner that undercuts the purposes of the statutory scheme. The consequence of permitting state courts, juries, and agencies to second-guess FDA approval decisions could be to slow the approval process and expose manufacturers to potentially massive liability simply for marketing FDA-approved products. This result is not permitted under the Supremacy Clause or section 360k(a) of the MDA.

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7. Manufacturers frequently are "repeat players" before the FDA, and want to maintain credibility before the agency to ensure the continued approvals of their products. As a result, they have a strong incentive not to defraud the agency or engage in other wrongful conduct during the approval process.

8. Congress's decision not to create a federal private right of action to enforce the FFDCA and MDA does not suggest that injured parties should be permitted to seek compensation under *state* law. To the extent that there are policy reasons for permitting injured parties to recover when FDA approval is wrongfully secured, preservation of the finality and uniformity of the federal regime mandates that such a remedy be granted by Congress, not haphazardly by the states.

II. RESPONDENTS' "INTENDED USE" POSITION CONFLICTS WITH THE USE OF THAT TERM IN THE FFDCA AND STATE-LAW CLAIMS BASED ON THAT POSITION ARE NECESSARILY PREEMPTED BY THE MEDICAL DEVICE AMENDMENTS OF 1976.

This case brings into sharp focus the problems with permitting state review of the federal approval process even where a federal standard is purportedly applied. At a minimum, respondents' claims would require state courts and juries to "look behind" the FDA decision-making process to determine what information was conveyed to the FDA; whether the FDA relied upon alleged misstatements; and whether, but for the alleged fraud, petitioner's bone screws would have been FDA-approved. As the Solicitor General has advised this Court, this examination itself would unduly impair the FDA review process. United States Br., at 16-18.

Respondents' claims also are preempted because their "intended use" theory would severely disrupt the federal regime. If respondents' subjective intent construction were to be adopted in even one jurisdiction, manufacturers would be forced to change their behavior during the approval stage in a manner that would severely undermine the "substantial equivalency" approval process and hinder the development of both breakthrough and follow-on devices and drugs.

A. Respondents' Claims Are Expressly Preempted Because They Would Impose A State-Law Requirement For "Intended Use" Disclosure That Is Different From, And In Addition To, The Requirement Under Federal Law.

As noted, respondents here assert that the FDA, as a result of petitioner's "fraud," "got it wrong" in approving petitioner's bone screws. In particular, respondents allege that petitioner misled the FDA regarding the screws' intended use, and that the FDA relied upon this misrepresentation in clearing the screws for market access. *Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d at 820. Because the screws were FDA-approved and available to physicians, physicians were able to use the screws off-label to perform pedicle surgeries, causing respondents' alleged physical injuries. *Ibid.*

Respondents' claims of fraud are based on the premise that federal law requires an FDA applicant to "truthfully" disclose any bona fide, subjectively intended or expected use for the device in question. Under federal law as defined by Congress, however, an FDA applicant's statement of "intended use" in its § 510(k) application is solely an *objective* description of the scope of marketing authority requested in the proposed labeling.

Federal law does not require a manufacturer to reveal its subjectively intended or expected uses for a device or drug in seeking FDA approval. Rather, the statement of "intended use," as defined by Congress, is a term of art objectively describing a manufacturer's requested authority for FDA-approved labeling and promotional claims. Congress's objective interpretation of intended use reflects its attempt to accommodate both the FDA's premarket review authority and the freedom of physicians to practice in accordance with their professional judgment.

Throughout the administration of the federal food and drug laws, "intended use" has been understood to refer only to the use set forth for a product in the product's labeling. The Food, Drug and Cosmetic Act of 1938 (FFDCA), Pub. L. No. 75-717, 52 Stat. 1040 (1938), established the requirement that, before the marketing of a new drug, a manufacturer must affirmatively demonstrate that the drug is safe "for use under the conditions prescribed, recommended, or suggested *in the proposed labeling thereof*." *Id.* § 505(d)(1), 52 Stat. at 1052 (codified as amended at 21 U.S.C. § 355(d)(1)) (emphasis added). This explicit limitation of premarket review to review of the uses claimed in the labeling illustrates Congress's clear intention to limit "intended uses" to uses labeled or promoted by the manufacturer, as opposed to all uses that the medical community may find attractive.

The FFDCA's legislative history recognized the essential tie between manufacturer claims and FDA authority to conduct premarket review:

> The use to which a product is to be put will determine the category into which it will fall. . . . *The manufacturer of the article, through its representations in connection with its sale, can determine the use to which the article is to be put.*

S. Rep. No. 73-493, at 2-3 (1934) (emphasis added).[9]

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9. Congress's subsequent amendments to the food and drug laws consistently adhered to the objective interpretation of "intended use." *See, e.g.*, Pub. L. No. 87-781, § 102(c), 76 Stat. 780, 781-82 (1962) (requiring manufacturers to make a premarket showing of effectiveness, as well as safety, for each "use . . . prescribed, recommended, or suggested in the labeling") (codified at 21 U.S.C. § 355(d)(1)); Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (creating an "Abbreviated New Drug Application" (ANDA) procedure under which generic versions of (Cont'd)

As with drugs, in regulating medical devices, Congress consistently has limited the definition of "intended use" to uses claimed in labeling or promotional materials. *See* 21 U.S.C. § 360c(a)(1)(C)(3)(A) (a Class III device's "effectiveness" is based on whether it is demonstrated that "the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device").

In fact, recently, Congress has explicitly declared that the statement of "intended use" in a premarket notification provision for a medical device is purely objective, and does not incorporate an applicant's subjective intent or expectations. In 1997, after the initiation of the present lawsuits against petitioner, Congress amended the FFDCA to include an instruction to the FDA that "[a]ny determination by [the FDA] of the intended use of a device [submitted for § 510(k) approval] shall be based upon the proposed labeling[.]" Food and Drug Administration Modernization Act, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (FDAMA) (codified at 21 U.S.C. § 360c(i)(1)(E)(i)). Thus, under FDAMA, the FDA may not consider a § 510(k) applicant's subjectively intended uses for a device.

The legislative history of FDAMA makes Congress's intent unmistakable. The Senate Report provided:

> With the "Medical Device Amendments of 1976," Congress intended that device classification and approval decisions be made based on the intended use of devices as described in labeling. . . .

(Cont'd)
pioneer drugs could receive expedited approval; limiting the FDA's authority to approve ANDAs to those where "the labeling proposed for the new drug is the same as the labeling proposed for the [pioneer] drug") (codified at 21 U.S.C. § 355(j)(2)(A)(v)).

> For premarket notification submissions, the labeling proposed in the submission will be controlling of a device's intended use. If the intended use is the same or sufficiently similar to the intended use of a predicate device, then the device may be found to be substantially equivalent to the predicate. *No considerations outside of the proposed labeling for the § 510(k) device should bear on the question of whether or not the proposed labeling of the newer device is compatible with the labeling of the predicate device.*

S. Rep. No. 105-43, at 27 (1997) (emphasis added).[10]

In sum, Congress has repeatedly and expressly restricted the definition of "intended use" to claims made in proposed

10. Although it refused to alter the objective understanding of "intended use," Congress enacted a provision directed at remedying the problem of potentially harmful uses that were *not* "intended uses." Specifically, Congress temporarily authorized the FDA, in reviewing a premarket notification submission, to require a manufacturer to include in the proposed labeling of its device a statement of "appropriate information" about an unclaimed use, where such a use is foreseeable and could pose a potential for harm. FDAMA, § 205, 111 Stat. at 2337 (codified at 21 U.S.C. § 360c(i)(1)(E)(i)); *see also* 21 U.S.C. § 360c(i)(1)(E)(iv) (five-year sunset on FDA authority).

An unclaimed use for which the FDA may require "appropriate information," however, still is not an "intended use" as that term of art has been defined by Congress. Rather, in enacting this provision, Congress explicitly segregated the "intended use" determination — which establishes the "substantial equivalency" necessary for § 510(k) approval — from the consideration of what, if any, further information should appear on the label regarding potentially dangerous off-label uses.

labeling.[11] To sustain respondents' theory of the case, however, state courts would have to reject this established construction and adopt a subjective interpretation of "intended use," thereby imposing disclosure obligations different from, and in addition to, those imposed under federal law. Any state action of this kind would clearly run afoul of section 360k(a) of the MDA.

B. Sustaining Respondents' Claims Would Severely Limit "Substantial Equivalency" Approvals For Medical Devices And Hinder Research And Development Of New Devices And Drugs.

By creating uncertainty regarding the meaning of "intended use," respondents' claims ultimately would hamper the research and development of new and follow-on medical devices and drugs.

Sustaining respondents' claims could severely hinder the ability of medical device manufacturers to seek expedited § 510(k) approval based on a device's "substantial equivalency" to a preexisting device. *See* 21 U.S.C. § 360e(b)(1)(B). Under § 510(k), a manufacturer seeking to market a new device may avoid the extended premarket

11. Four members of this Court, dissenting in *Food & Drug Administration, et al. v. Brown & Williamson Tobacco Corp., et al.*, __U.S.__, 120 S. Ct. 1291, 146 L. Ed. 2d 121 (2000), took the position that "intended use" can, for purposes of determining the FDA's jurisdiction over drugs, incorporate uses that are fostered or expected by manufacturers. 120 S. Ct. at 1320-22, 146 L. Ed. 2d at 157-59 (Breyer, J., dissenting). The dissent's discussion, however, concerned the FDA's alleged authority to regulate products whose objectively "intended uses" are discernible from the circumstances surrounding the products' *marketing*. 120 S. Ct. at 1320, 146 L. Ed. 2d at 157. *Brown & Williamson* did not involve the disclosure requirements for FDA approval. None of the regulations cited by the dissent in that case suggests that the "intended use" statement in an application for § 510(k) approval incorporates a manufacturer's future expectations or desires regarding the product's use.

approval process by demonstrating that the device is "substantially equivalent" to a predicate device. *Id.*; *see also Medtronic*, 518 U.S. at 477-79. The manufacturer must submit a premarket notification to the FDA describing, among other things, the "intended uses" of the device. 21 C.F.R. § 807.92(a)(5). If the FDA determines that the proposed device is "substantially equivalent" to its predicate for the specified "intended uses," it will grant approval. *Id.* § 807.100.

Importantly, a manufacturer may not secure § 510(k) approval for a device with materially different or additional "intended uses" from those of its predecessor. 21 U.S.C. § 360c(i)(1)(A) ("substantial equivalence" of devices requires that the devices have the same intended uses); 21 C.F.R. § 807.100(b)(1). Thus, where a new device has uses in addition to those of its predicate, the manufacturer is precluded from seeking expedited approval.

In the § 510(k) context, situations frequently arise where uses have developed for a predicate device beyond those approved by the FDA. Once a predicate device has been placed on the market, medical practitioners are free to adopt such off-label uses. By the time "substantial equivalency" approval is sought, these off-label uses are often documented in scientific literature, making them clearly foreseeable to § 510(k) applicants.

If respondents' claims are not preempted, a § 510(k) applicant could face potentially massive state fraud liability if it failed to list as "intended uses" all foreseeable uses of the device it wished to market. Plaintiffs claiming to be harmed in connection with a foreseeable off-label use could (and likely would) allege, as here, that the manufacturer subjectively intended the device to be put to that use — either in lieu of, or in addition to, the listed "intended

use" — and defrauded the FDA by failing to disclose such intent.[12]

If, to protect themselves from claims such as respondents', manufacturers disclosed all potential uses as "intended," they would be ousted from the § 510(k) process and forced to submit their devices instead to the premarket approval process.[13] This would radically change the current trend in device approval applications, *see* Food and Drug

12. The fact that respondents in this case assert that petitioner committed "fraud on the FDA" by providing an allegedly *pretextual* "intended use" statement would not alter this result. As a practical matter, a manufacturer could face "fraud on the FDA" claims any time an off-label use allegedly caused harm, regardless of whether such claims were based on an allegedly pretextual "intended use" statement or on an alleged failure to disclose an additional subjectively intended use. The manufacturer also would face potentially enormous litigation costs associated with either type of "fraud on the FDA" claim. Here, for example, the issue of whether petitioner falsely asserted a pretextual "intended use" for its bone screws is inherently factual in nature. Its resolution would require a determination of, among other things, (1) whether petitioner had a bona fide intent to market the screws in accordance with their listed "intended use"; (2) whether petitioner in fact intended for the screws to be marketed for pedicle surgeries; (3) precisely what was disclosed or not disclosed to the FDA; and (4) whether the FDA was misled by petitioner's alleged misrepresentation.

13. A manufacturer could not defend itself from claims such as these merely by disclosing to the FDA all foreseeable uses, without seeking either approval or "contraindication" labeling therefor. This is because, with respect to any off-label use for which labeling is *not* sought, plaintiffs could assert, as here, that the manufacturer subjectively intended the use to be adopted, yet failed to reveal such intent to the FDA. As a result, a manufacturer's only affirmative defenses to such a claim would be either: (1) that it *did* subjectively intend for the off-label use in question to be adopted, *and* disclosed such intent to the FDA by seeking approval for that use; or (2) that it *did not* intend the use, and foreclosed it by seeking contraindication labeling.

Admin., Center for Devices and Radiological Health, Off. of Device Evaluation, *Annual Report: Fiscal Year 1998* 21 (reporting that, during fiscal year 1998, 4,623 original § 510(k) applications were filed, as compared with 55 original premarket approval applications); *Medtronic*, 518 U.S. at 479-80 (reporting that, in 1990, 80% of new Class III devices were approved through the § 510(k) mechanism), and would thwart the salutary legislative purposes for which the expedited approval scheme was enacted. 518 U.S. at 478 (noting that the scheme was intended to "prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market").

In addition to directly undermining the § 510(k) process, sustaining respondents' claims would impede the approval of new medical devices. Because the threat of state fraud liability would force manufacturers to disclose and rigorously test for all potential uses and seek labeling therefor, these claims would work to significantly slow the already laborious premarketing approval process. This adverse consequence conflicts with the MDA's goal of ensuring the ready availability of safe and effective medical devices. *See* H.R. Rep. No. 94-853, at 12 (1976).

The adverse effects of allowing respondents' claims also could spill over into the drug approval context. Applicants for FDA approval of a drug must list the drug's intended indications. *See* 21 C.F.R. § 314.50(c)(2). Claims such as respondents' therefore could be asserted any time a foreseeable off-label use caused harm. To avoid exposure to such claims, drug approval applicants presumably would be forced to shoulder the same pre-approval burden as medical device applicants — namely, testing and seeking labeling for all known or foreseeable uses of proposed drugs. Thus,

as with medical devices, the existence of respondents' claims likely would raise costs for and slow all drug approvals. Generic drug applications, which require manufacturers to use labeling identical to the pioneer predecessor's, would be particularly affected, as off-label uses of pioneer drugs are widespread. *See* Rabin, 88 Geo. L.J. at 2078 (off-label uses of drugs are "critical to adequate health care" and are widespread in the pediatric and cancer fields). The required disclosure of such uses would foreclose access to the Abbreviated New Drug Application process under the FFDCA. *See* 21 U.S.C. § 355(j). The end result — diminished availability of both pioneer and generic medicines — would be directly at odds with Congressional intent. *See, e.g.*, H.R. Rep. No. 98-857, pt. 1, at 14 (1984) (Abbreviated New Drug Application process was intended "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962").

C. Sustaining Respondents' Claims Would Impede The Dissemination Of Information Regarding Off-Label Uses Of Devices And Drugs.

Respondents' intent theory also would disrupt the delicate federal regulatory balance that has been struck with respect to the proper role of manufacturers in the dissemination of information regarding off-label uses.

Congress recognizes the importance of limiting federal regulatory interference with the practice of medicine by health care professionals, and specifically with physicians' freedom to use medical devices and drugs off-label. With respect to medical devices, Congress has declared:

> Nothing in [the FFDCA] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.

21 U.S.C. § 396. As its legislative history explains, this section was intended to restrict regulatory interference with off-label uses of devices. *See* H.R. Conf. Rep. No. 105-399, at 219 (1997) ("The conference agreement includes a provision intended by the conferees to emphasize that the FDA should not interfere in the practice of medicine. Specifically, the conferees note that the off-label use of a medical device by a physician using his or her best medical judgment in determining how and when to use the medical product for the care of a particular patient is not the province of the FDA").

Off-label uses have long been viewed by Congress and the FDA as a rational and beneficial part of the practice of medicine. *See, e.g.*, 59 Fed. Reg. 59820, 59821 (1994) (the FDA has long held that "'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact[,] reflect approaches to drug therapy that have been extensively reported in medical literature"); *More Information for Better Patient Care: Hearings on S. 1477 Before the Senate Comm. on Labor and Human Resources*, 104th Cong. 81 (1996) (Statement of William B. Schultz, FDA Deputy Comm'r for Policy) ("[O]ff label uses of approved products are appropriate, rational, and accepted in medical practice. FDA knows that there are important off label uses of approved drugs"). Such uses are prevalent, and even predominant, in important fields such as oncology and pediatrics. *See* Rabin, 88 Geo. L.J. at 2078; *see also Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 56 (D.D.C. 1998), *order amended*, 36 F. Supp. 2d 16 (D.D.C. 1999), *appeal dismissed, judgment vacated in part on other grounds by Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). In the case of AIDS, experts report that between ninety and one hundred percent of pharmaceutical treatments, including the antiretroviral

"cocktail" therapies, are off-label. *See* Kenneth P. Berkowitz, et al., *Congress Tries to Bridge the 'Label Gap' But Nobody Is Cheering*, Med. Mktg. & Media, Jan. 1998, at 39-40. Off-label uses frequently constitute the standard of good medical care. *See Washington Legal Found.*, 13 F. Supp. 2d at 56.

Congress had a compelling practical reason for structuring the FFDCA to allow off-label uses — medicine simply moves faster than the FDA possibly can:

> New uses for drugs are often discovered after FDA approves the package inserts that explain a drug's approved uses. Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses.

United States v. Algon Chem., Inc., 879 F.2d 1154, 1163 (3d Cir. 1989) (quoting *Chaney v. Heckler*, 718 F.2d 1174, 1180 (D.C. Cir. 1983), *rev'd on other grounds*, *Heckler v. Chaney*, 470 U.S. 821 (1985)). *See* William L. Christopher, *Off-Label Drug Prescription: Filling the Regulatory Vacuum*, 48 Food & Drug L.J. 247, 261 (1993) (the FDA "could not review drugs . . . at a pace equal to that at which physicians discover off-label uses").

The FDA has recognized the need for disseminating adequate information regarding off-label uses and has attempted to regulate the manner and extent to which manufacturers can participate in the development and dissemination of such information. *See Washington Legal Found.*, 13 F. Supp. 2d at 56-58. As Judge Cowen stated in his dissent below, given the FDA's acceptance of off-label uses, "difficult and subtle balancing is called for in evaluating manufacturers' roles in the creation and distribution of information about [such] uses[.]" 159 F.3d at 831;

see also 59 Fed. Reg. 59820, 59823 (1994) (the FDA has recognized "the delicate balance required to accommodate the need for industry-supported scientific and educational activities and the statutory mandate that products be safe and effective for their intended uses").

Sustaining respondents' claims would wreak havoc on this balancing by permitting state courts and juries to force manufacturers, to the extent they are able, to eliminate off-label uses entirely. As discussed above, to avoid massive state "fraud" liability, manufacturers would be forced to include as many uses as possible "on-label." Further, the threat of state liability would discourage manufacturers from providing information regarding and contributing to efforts to study alternative uses of their products, since such efforts might be viewed as evidence of manufacturers' subjective intent to market their products for such uses. Thus, sustaining respondents' claims could curtail the information flow relating to off-label uses in a sweeping and misdirected manner that is discordant with the federal regulatory scheme, and further compels reversal of the decision below.

CONCLUSION

Claims such as respondents' — which are premised on the alleged invalidity of an FDA approval determination — are preempted by federal law. Allowing such claims would improperly impose an additional layer of state review of FDA approval decisions, undermining the finality and certainty of the federal approval scheme. Sustaining respondents' claims also would introduce a new theory of "intended use," which would distort manufacturer behavior and reduce the availability of beneficial medical devices and drugs to the public.

For all of the foregoing reasons, this Court should reverse the lower court's decision.

Respectfully submitted,

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